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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,900	10/06/2003	Mark A. Hoffman	CRNI.107060	3801

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SHOOK, HARDY & BACON L.L.P.
Intellectual Property Department
2555 GRAND BOULEVARD
KANSAS CITY, MO 64108-2613

EXAMINER

CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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12/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/679,900

Applicant(s)

HOFFMAN, MARK A.

Examiner

Lori A. Clow, Ph.D.

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 3-10, 16, 33, 39 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 11-15, 17-32, 34-38, 40-49, and 51-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☐ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application |
| 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) ☐ Other: _____ |

DETAILED ACTION

Applicants' response, filed 1 October 2007, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-54 are currently pending. Claims 3-10, 16, 33, 39, 50 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 27 November 2006. Claims 55-64 have been cancelled. Claims 1, 2, 11-15, 17-32, 34-38, 40-49, and 51-53 are examined herein.

Specification and Sequence Compliance

It is noted that Applicant has filed a Sequence Listing in Computer Readable Form (CRF) to overcome the requirement for sequence compliance set forth in the previous Office Action. The CRF is proper and has been entered. It is also noted that Applicant has amended the specification at paragraph [0015] to include SEQ ID NO: 1. The amendment is proper and has been entered.

Applicant is kindly reminded that Figure 6 also includes a nucleotide sequence. The sequence is identical to that of Figure 5 and therefore no new sequence listing is required for the sequence of Figure 6. However, the specification should be amended to include the identifier "SEQ ID NO:1" in the description of Figure 6.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 2, 11-15, 17-32, 34-38, 40-49, and 51-53 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, for the reasons set forth in the previous Office Action and re-iterated below. The newly recited portions of the rejection are necessitated by amendment.

Claims 1 is drawn to a method in a computing environment for documenting mutations comprising steps that do not include a physical transformation of matter. As emphasized by the New Interim Guidelines the claims are evaluated for providing a practical application. A practical application is claimed if the claimed invention physically transforms an article or physical object to a different state or thing, or if the claimed invention otherwise produces a concrete, tangible, and useful result. In the instant case, a physical transformation of matter is not provided, as the instant claims merely encompass non-physical (i.e. *in-silico*) method steps which do not result in a physical transformation of matter.

Therefore, the claims must be evaluated for providing a practical application that produces a concrete, tangible and useful result. The focus is not on the steps taken to achieve a particular result, but rather the final result achieved by the claimed invention. A claim may be statutory where it recites a result that is concrete (i.e. reproducible), tangible (i.e. communicated to a user), and useful (i.e. a specific and substantial). In the instant case, claim 1 does not recite a tangible result such that it is useful to one skilled in the art. Claim 1 is directed to merely

receiving information, disassembling that information, storing the information, and presenting the mutation within a computer environment. For these reasons, the instant claims are not statutory.

Claims 34, 46, 53, and 54 are drawn to a computer system for documenting mutations. Claims 51 and 52 are drawn to a computer-readable medium. In the instant claims the “computer system” and “computer-readable medium” constitute nonfunctional descriptive material, as no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material, i.e. abstract ideas, stored in a computer-readable medium, in a computer, does not make the claims statutory. Further, data structures, as in a “program” are descriptive material, *per se* and are not statutory because they are not capable of causing a functional change in the computer. See, e.g., Warmerdam, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure *per se* held nonstatutory). Computer programs are viewed as computer listings, *per se*, i.e., the description or expression of the programs, are not physical things. They are neither computer components nor statutory processes, as they are not “acts” being performed. Such claimed computer programs do not define any structural and functional interrelationships between the computer program and the other claimed elements of a computer that permit that computer program’s functionality to be realized.

This rejection could be overcome by amending the claims to recite that a result of the method is “displayed” or “outputted” (e.g. output to a user or a display), or by amending the claims to include a step of a physical transformation of matter (e.g. assay), provided such is supported in the specification as originally filed. For an updated discussion of statutory

considerations with regard to non- functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter in the MPEP 2106, Section IV.

Response to Applicant's Arguments Pertaining to 35 USC 101

1. Applicant argues that with respect to claim 1, 29, 51, and 52, the claims have been amended “such that the mutation is presented using one or more standards, *e.g.*, the user-preferred standard, the published standard, or a combination thereof”. Applicant submits that “independent claims 1, 29, 51, and 52 produce a tangible result”.

This is not persuasive. The step of “presenting the mutation using the user-preferred standard” as is now amended, does not provide a tangible result that is useful to one skilled in the art. Rather, the instant claims could merely encompass *in silico* data manipulation with no specific output, such as output to a user. The tangible requirement does require that the claim must recite more than a 101 judicial exception, in that the process claim must set forth a practical application of that 101 judicial exception to produce a real-world result. Benson, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because no “substantial practical application.”). In the instant case, no real-world result is set forth.

2. Applicant argues that “with respect to independent claims 34, 46, 53, and 54..the claims are directed to a computer system” Applicant recites *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557 (*en banc*) stating that “a machine claim is statutory when...a specific machine is being claimed.

This is not persuasive. As is stated in the Guidelines for Patent Eligible Subject Matter in the MPEP 2106, Section IV, the following analysis is applied:

“Determining whether the claim falls within one of the four enumerated categories of patentable subject matter recited in 35 U.S.C. Sec. 101 (process, machine, manufacture or composition of matter) **does not end the analysis because claims directed to nothing more than abstract ideas (such as mathematical algorithms), natural phenomena, and laws of nature are not eligible and therefore are excluded from patent protection.** Diehr, 450 U.S. at 185, 209 USPQ at 7; accord, e.g., Chakrabarty, 447 U.S. at 309, 206 USPQ at 197; Parker v. Flook, 437 U.S. 584, 589, 198 USPQ 193, 197 (1978); Benson, 409 U.S. at 67-68, 175 USPQ at 675; Funk, 333 U.S. at 130, 76 USPQ at 281. “A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.” Le Roy, 55 U.S. (14 How.) at 175. Instead, such “manifestations of laws of nature” are “part of the storehouse of knowledge,” “free to all men and reserved exclusively to none.” Funk, 333 U.S. at 130, 76 USPQ at 281.”

It is also noted that Alappat states the following:

Alappat, 33 F.3d at 1543, 31 USPQ2d at 1556-57: “certain types of mathematical subject matter, standing alone, represents nothing more than abstract ideas until reduced to some type of practical application, and thus that subject matter is not, in and of itself, entitled to patent protection.”).

Further, Alappat stated that:

“A claim limited to a machine or manufacture, which has a practical application, is statutory. In most cases, a claim to a specific machine or manufacture will have a practical application. See Alappat, 33 F.3d at 1544, 31 USPQ2d at 1557 (“the claimed invention as a whole is directed to a combination of interrelated elements which combine to form a machine for converting discrete waveform data samples into anti-aliased pixel illumination intensity data to be displayed on a display means. This is not a disembodied mathematical concept which may be characterized as an ‘abstract idea,’ but rather a specific machine to produce a useful, concrete, and tangible result.”)

However, in the instant case, the system, as a whole, is not directed to a combination of interrelated elements that combine to provide a "result" (i.e. display or output) such that the result is deemed useful, concrete or tangible. The claims therefore remain non-statutory.

35 USC 101-Utility/35 USC 112, 1st paragraph

The outstanding rejections for lack of utility under 35 USC 101/35 USC 112, 1st paragraph have been withdrawn in view of Applicant's arguments and amendments to the claims in which mutations are presented.

35 USC 112, 2nd paragraph

The outstanding rejection under 35 USC 112, 2nd paragraph has been withdrawn in view of the claim amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 11, 13, 14, 17-24, 26, 27, 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by den Dunnen et al. (Human Mutation (2000) Vol. 125, pages 7-12; PTO Form 1449 reference), for the reasons set forth in the previous Office Action and re-iterated below.

The instant claims are drawn to a method, system and computer medium for documenting mutations.

Den Dunnen teaches a codified nomenclature system for complex mutations (abstract). In regard to claims 1 and 29, den Dunnen teaches receiving mutation information and disassembling/assembling it into element, such as insertion etc... information (page 7, column 2).

The mutation information contains substitution information, as in claim 2 (page 7, column 2).

Unique identifiers are established for each mutation (page 8, column 2), as in claim 11.

The genetic information includes nucleotide or amino acids (page 8, column 1) (claims 13 and 18).

Standards are user defined (entire article) (claims 14, 30, 31).

Particular sequenced genetic information is taught, as in claim 17 (page 8, column 2).

Reference sequences are provided with particular mutation information and position information as in claims 19-23 (page 8, column 2).

In regard to claim 24, mutation type is taught at page 9, for example (see Table 1).

In regard to claim 26, the mutation information is for humans (page 11, column 1).

In regard to claim 27, the information could be for a specific patient, as in a MD patient (page 11, column 1).

Response to Applicant's Arguments Pertaining to 35 USC 102(b)

1. Applicant states that "independent claim 1, as amended herein, relates to a method in a computing environment for documenting mutations..." Applicant argues that "the [den] Dunnen reference describes suggestions for reporting complex mutations in a unified manner". Applicant further states that "although the [den] Dunnen reference discusses mutation nomenclature, the [den] Dunnen reference does not teach or suggest *disassembling* the mutation information into discrete elements, *storing* the discrete elements, or *presenting* the mutation using either a user-preferred standard or published standard. Rather, the [den] Dunnen reference merely provides suggestions for mutation nomenclature. There is no discussion of disassembling the mutation information into discrete elements".

This is not persuasive. As was previously stated, den Dunnen teaches receiving mutation information and disassembling/assembling it into element, such as insertion etc... information (page 7, column 2). In addition, den Dunnen discusses "tabular listing" which can reasonably be interpreted as "discrete elements". Specific elements about mutations are outlined at page 8, column 1 to column 2, which are elements of dissembled information about mutation, therefore reading on the limitations set forth in the instant claims, as defined by the instant specification, which states that disassembling information into discrete elements can include, for example, elements that include molecule type (DNA, cDNA, RNA, and protein) (page 11, paragraph [0034]).

As to the storing and presenting of the data, it is inherent that a database would store information as well as present it, as is intended by a "nomenclature system" as taught by den Dunnen.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 34-37, 40-49, 51-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over den Dunnen et al. (Human Mutation (2000) Vol. 125, pages 7-12; PTO Form 1449 reference), as applied to claims 1, 2, 11, 13, 14, 17-24, 26, 27, 29-31, in view of DNA Star Sequence Analysis System (2003; PTO Form 1449 reference), for the reasons set forth in the previous Office Action and re-iterated below.

Den Dunnen teaches the mutation documentation of claims 1, 2, 11, 13, 14, 17-24, 26, 27, 29-31, as stated above. Den Dunnen does not specifically teach a computer system for performing the methods. However, the DNA Star system is a comprehensive suite for sequence analysis software that is able to integrate various sequence information into a standalone network as a convenient way to compile diverse types of data (see description). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used the DNA

Star compilation system to automate the method of mutation documentation of den Dunnen. One would have been motivated to do so because the DNA Star system is useful for comparing genomic sequence data and comparing sequence data (see description). With the amount of information available for mutations, as in the mutation documentation and nomenclature of den Dunnen, one would have been motivated to automate the method for a more efficient way of data curation.

Response to Applicant's Arguments Pertaining to 35 USC 103

1. Applicant argues that the den Dunnen reference fails to teach or suggest all of the claimed features of the rejected independent claims.

This is not persuasive for the reasons set forth above pertaining to the 35 USC 102(b) rejection and the den Dunnen reference.

Applicant argues further "that the DNA Star reference does not teach or suggest *disassembling* the mutation information into discrete elements, *storing* the discrete elements, or *presenting* the mutation using either a user-preferred standard or published standard. Rather the DNA Star reference merely mentions analysis tools".

This is not persuasive. The DNA Star reference is cited in combination with the den Dunnen reference. Den Dunnen teaches the claim elements of *disassembling* the mutation information into discrete elements, *storing* the discrete elements, or *presenting* the mutation using either a user-preferred standard or published standard, as stated above. Further, as stated above, the DNA Star reference is relied upon to teach a system that is useful for comparing genomic sequence data and comparing sequence data (see description) and that one would have

been motivated combine the teachings of den Dunnen with DNA Star because the DNA Star system is useful for comparing genomic sequence data and comparing sequence data. With the amount of information available for mutations, as in the mutation documentation and nomenclature of den Dunnen, one would have been motivated to automate the method for a more efficient way of data curation.

Claims 15, 28, 32, 38, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over den Dunnen et al. (Human Mutation (2000) Vol. 125, pages 7-12; PTO Form 1449 reference), as applied to claims 1, 2, 11, 13, 14, 17-24, 26, 27, 29-31, in view of Cotton et al. (Human Mutation (2000) Vol. 15, pages 16-21), for the reasons set forth in the previous Office Action and re-iterated below.

Den Dunnen teaches methods of mutation documentation as recited above. Den Dunnen does not specifically teach published standards of the Human Genome Association or the patient specifically in connection with a mutation. However, Cotton teaches the importance of adhering to standards when creating a mutation database (abstract). Human Genome Association has established those standards in a widespread initiative such that quality of mutation content would be constant (page 19, column 2). Furthermore, Cotton teaches associating specific patient mutations (page 18, Table 1). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have employed the Human Genome Association standards in the mutation documentation methods of den Dunnen. One would have been motivated to do so because the entire basis of the mutation documentation of den Dunnen is for consistent quality among gene mutation nomenclature (abstract).

Response to Applicants Arguments Pertaining to 35 USC 103

1. Applicant argues that the Cotton reference does not teach or suggest *disassembling* the mutation information into discrete elements, *assembling* the mutation information utilizing the discrete elements, *storing* the discrete elements, or *presenting* the mutation using either a user-preferred standard or published standard.”

This is not persuasive. As is stated above, den Dunnen is relied upon to teach the elements of *disassembling*, *assembling*, *storing*, and *presenting*, as is stated above. It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have employed the Human Genome Association standards in the mutation documentation methods of den Dunnen. One would have been motivated to do so because the entire basis of the mutation documentation of den Dunnen is for consistent quality among gene mutation nomenclature (abstract).

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete

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service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

LORI A. CLOW, PH.D.
PRIMARY EXAMINER



December 20, 2007
Art Unit 1631